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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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W. Wayne Liauh
Law Offices of Liauh & Assoc.
4224 Waialae Avenue
Suite 5-388
Honolulu, HI 96816

EXAMINER

JOLLEY, KIRSTEN

ART UNIT

PAPER NUMBER

1762

8

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/832,048

Applicant(s)

SHEU ET AL.

Examiner

Kirsten Crockford Jolley

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Specification

1. The amendment filed April 4, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is from the new paragraph added on page 7, after line 25: "In summary, the present invention presents a new method to dissolve nucleic acid completely in a water-insoluble medium" and "Because the medium is water-insoluble, it would not be easily erased. Therefore, the labeling for authentication could last for a long period of time."

These newly-added statements contain new matter for several reasons. The specification, as originally filed, does not state that the nucleic acid was *completely dissolved* in a medium; in contrast, the specification merely stated that the nucleic acid was *mixed* with the medium. Additionally, while the Examples disclose the use of polycarbonate as a medium (which is inherently water-insoluble), the specification does not disclose the use of all water-insoluble mediums. The added disclosure of the use of all water-insoluble mediums specifically excludes water-soluble mediums, and the original disclosure does not indicate that the inventor was in possession of the exclusion of water-soluble mediums at the time of the invention. Finally, the specification, as originally filed, does not disclose that the medium would not be easily erased, or that it could last for a long period of time.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 16-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 16 and 26, line 2 of each, the limitation “water-insoluble medium” appears to be new matter. As discussed above, the Examples disclose the use of polycarbonate as a medium (which is inherently water-insoluble), however the specification does not disclose the use of all water-insoluble mediums. The added disclosure of the use of all water-insoluble mediums specifically excludes water-soluble mediums, and the original disclosure does not indicate that the inventor was in possession of the exclusion of water-soluble mediums at the time of the invention.

In claims 16 and 26, line 3 of each, the limitation “dissolving nucleic acid *in a second solvent* to form a second mixture [emphasis added]” appears to be new matter. While it is noted the Examples disclose dissolving nucleic acid in ethanol and acetone, the body of the specification (excluding the Examples) does not disclose dissolving nucleic acid in a solvent at all. Therefore, Applicants have support in the specification for dissolving nucleic acid in acetone and ethanol, however there is not support for dissolving nucleic acid in *any solvent*. While

Art Unit: 1762

claims 21-22 and 31-32 claim “wherein said second solvent comprises ethanol” and “wherein said second solvent comprises acetone”, it is noted that the claims use broad “comprising” language therefore the claims are open-ended and do not cure the deficiencies of claims 16 and 26.

In claims 16 and 26, lines 8-10 and 7-9 respectively, the limitations “wherein said water-insoluble medium is an inert medium which is not deteriorative to said article or substance, and said second solvent mediates solubility between said first mixture and said nucleic acid” appears to be new matter because the Examiner could not locate these disclosures in the specification.

Examiner's Suggestions

4. In claim 18, line 1, the word --substance-- appears to be missing between “polymeric” and “comprises.”
5. In claim 26, line 1, the Examiner notes that the term “liquid article” is awkward language.
6. In claim 28, line 2, “selected from a group consisting of polycarbonate” is confusing because only one chemical is not a “group”.
7. In claim 36, line 1, in the phrase “authenticating a labeling”, “labeling” is not an English word.
8. In claim 36, line 2, the word --acid-- appears to be missing between “nucleic,” and “said.”
9. In claim 36, line 4, there is insufficient antecedent basis for “said solvent containing said labeling” in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 36-39 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 477 220

B1.

EP '220 discloses a method of authenticating an article or substance labeled with a nucleic acid taggant. EP '220 discloses the steps of: washing or extracting a portion of the article or substrate with distilled water, a buffered solution, or phenol/chloroform extractants, which are all solvents; and sampling and detecting nucleic acid taggant from the solvent (page 4, lines 22-29). Additionally, see Examples on page 6. As to claim 37, EP '220 teaches that a polymerase chain reaction (PCR) may be used to detect the nucleic acid (page 4, lines 30-34). As to claims 38-39, EP '220 teaches the use of chloroform as the solvent, which is an organic solvent.

Response to Arguments

12. Applicant's arguments have been considered but are moot in view of the new grounds of rejection. It is noted that the prior art does not teach the method of claims 16-35 as currently written. The closest prior art of EP '220 teaches, in Example B on page 6, a water-insoluble medium (Span 80) in combination with nucleic acid and solvent. However, the reference does not teach dissolving the nucleic acid in a solvent whereby the solvent mediates solubility

Art Unit: 1762

between the first mixture (formed of a first solvent and water-insoluble medium) and said nucleic acid. However the claims are rejected under 35 USC 112, 1st paragraph as discussed above.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kirsten Crockford Jolley whose telephone number is 703-306-5461. The examiner can normally be reached on Monday to Thursday and every other Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Art Unit: 1762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1193.

kcj

June 18, 2003



TIMOTHY MEEKS
PRIMARY EXAMINER